



REGULATORY PHARMACEUTICAL FELLOWSHIP

Government | Industry | Academia

2018-2020

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**PURDUE
UNIVERSITY**












Lilly



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FELLOWSHIP OBJECTIVES

- ❖ Train selected candidates via a two-year, knowledge-based program on medical and regulatory aspects of drug information, medication safety, or advertising and promotion
- ❖ Maintain and enhance a scientific link among the Food and Drug Administration (FDA), academia, and the pharmaceutical industry
- ❖ Offer opportunities for fellows to understand the complex participating roles of the FDA and the pharmaceutical industry in the delivery of drug information and the regulatory oversight of prescription drug marketing and safety practices
- ❖ Provide participants the opportunity to experience careers in the areas of government, academia, and industry
- ❖ Qualify program graduates to pursue careers in each unique practice area
- ❖ **The 2018 – 2020 program cycle is recruiting the following fellowship tracks:**
Drug Information and Medication Safety



PROGRAM DIRECTOR



Lindsay E. Wagner, PharmD

Lieutenant Commander, U.S. Public Health Service

Team Leader

Division of Drug Information
Food and Drug Administration

Drug Information Track Preceptor
Past Fellow: 2009 - 2011 Cycle

Lindsay received her PharmD degree from the Albany College of Pharmacy and Health Sciences in 2009 and completed the Regulatory Pharmaceutical Fellowship in drug information in 2011. Following the fellowship, Lindsay accepted a position with the Division of Drug Information (DDI) as a civilian Consumer Safety Officer. In 2012, Lindsay joined the active duty service of the U.S. Public Health Service Commissioned Corps. In 2014, she joined DDI's Senior Management Team as a Team Leader and in 2015 received a promotion to the rank of Lieutenant Commander.

In her current role, she leads a team of pharmacists and other experts to ensure timely, complete, and accurate responses to inquiries from around the globe on issues related to drug products. Lindsay also provides leadership for many programs including FDA's drug-related content on Facebook, the network of drug information pharmacists known as the Global Alliance of Drug Information Specialists on LinkedIn, CDER's Expanded Access program in DDI including emergency request procedures, drug information reports for tentatively approved PEPFAR products, and policies and procedures important to MedWatch and adverse event reporting. Lindsay is a major contributor to DDI's written communication efforts, including writing campaign responses, web updates, and social media posts. Lindsay trains and mentors student pharmacists, non-pharmacy post-graduate fellows, and the drug information track fellows of this program.

DRUG INFORMATION TRACK TIMELINE

DRUG INFORMATION TRACK #1

DRUG INFORMATION TRACK #2

July 2018

01

Indianapolis, IN
6 Months

PURDUE
UNIVERSITY

College of
Pharmacy

Jul. 2018- Dec. 2018

02

Titusville, NJ
12 months

janssen
PHARMACEUTICAL COMPANY
a Johnson & Johnson company

Medical
Information

Jan. 2019- Dec. 2019

03

Silver Spring, MD
6 Months

FDA

Division
of Drug
Information

Jan. 2020- Jun. 2020

01

Indianapolis, IN
6 Months

PURDUE
UNIVERSITY

College of
Pharmacy

Jul. 2018- Dec. 2018

02

Silver Spring, MD
6 months

FDA

Division of
Drug
Information

Jan. 2019- Jun. 2019

03

Northbrook, IL
12 months

astellas

Medical
Information

Jul. 2019- Jun. 2020

June 2020

DRUG INFORMATION TRACK OVERVIEW

Purdue

The 6-month portion will expose the fellow to academia and the responsibilities of institutional-based drug information centers. The program offers experience with the provision of drug information at IU Health and Purdue's Center for Medication Safety Advancement (CMSA). Fellows will conduct a research project suitable for presentation at a national meeting and publication in a peer-reviewed pharmacy journal and participate in the Indiana Pharmacy Teaching Certificate Program. The fellow gains significant experience in academia, providing didactic and experiential training to student pharmacists.

Janssen

The 12-month rotation provides the opportunity for the fellow to gain experience as a member of a medical information team in a pharmaceutical industry setting. The program allows the fellow to develop skills related to development and delivery of drug information to healthcare professionals, payors, consumers, and business partners through a variety of methods. The fellow will have the option to participate in collaborative inter- and intra-departmental projects, mentor pharmacy students, and network with other pharmacists within the organization and through a pharmacist-focused resource group.

Astellas

During the 12-month rotation, the fellow will develop skills related to development and delivery of drug information to external stakeholders, such as healthcare professionals, payors, consumers, as well as internal stakeholders, including pharmaceutical representatives, medical science liaisons and the Medical Information team. The fellow will be given opportunities to develop the skills for marketed products as well as newly launched and/or investigational products in therapeutic areas, including oncology, urology/nephrology, immunology and neuroscience.

FDA

The 6-month FDA rotation will provide an opportunity for fellows to refine their drug information skills in a regulatory setting. Fellows will respond to dozens of drug information inquiries from patients, health care professionals, and regulated industry received daily. Fellows will create and disseminate content on Twitter and LinkedIn and respond to questions on Facebook as part of FDA's Social Media team. Fellows will work on video, podcast, and listserv content as well. Fellows will serve as liaisons to specific Review Divisions and assist with a number of high-profile initiatives including the Generic Drug User Fee Amendments, Expanded Access, and writing campaign responses.

DRUG INFO PRECEPTOR-PURDUE

Amy H. Sheehan, PharmD

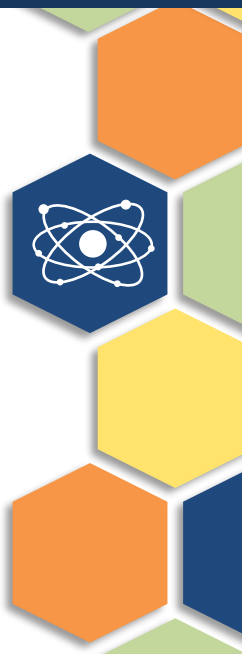
Associate Professor, Pharmacy Practice

Purdue University

College of Pharmacy



Amy graduated from the University of Cincinnati where she received her BS and PharmD degrees. After graduation, she pursued post-doctoral training with the National Institutes of Health. For the past 19 years, Amy has been responsible for didactic instruction of the principles of drug information within the professional degree program at Purdue University. Amy's practice site is the IU Health Center for Medication Management, where she contributes to the provision of comprehensive drug information services. Amy also serves as a preceptor for student pharmacists, pharmacy residents, and pharmacy fellows.



DRUG INFO PRECEPTOR-ASTELLAS

Jeanette Jiang, PharmD

Associate Director,

Medical Information

Astellas



In her current position at Astellas, Jeanette has oversight of products in the cardiovascular, infectious disease and immunology therapeutic areas. Her responsibilities include development and maintenance of medical communications, including, but not limited to, medical information standard content, product bibliographies and scientific affairs presentations and content. Jeanette also reviews commercial materials to assess if the claims accurately represent current scientific and medical practices supported by substantial evidence. Throughout her career at Astellas, Jeanette has served as a preceptor to Pharm D. students and residents from a variety of universities. She also has served on a subcommittee for **Pharma Collaboration for Transparent Medical Information (phactMI™)**, which is a collaboration of Medical Information (MI) departments at pharmaceutical companies that are dedicated to supporting healthcare professionals in their commitment to provide quality patient care.



DRUG INFO PRECEPTORS- JANSSEN



Samina Ali, PharmD

**Associate Director,
Medical Information**
Janssen Scientific Affairs, LLC

Samina earned her BS and PharmD degrees from Rutgers University College of Pharmacy and completed an ASHP-accredited Hospital Pharmacy Practice Residency at the Mount Sinai Medical Center in New York City. Throughout her 15 plus-year career at Janssen, Samina has led and supported Medical Information activities for multiple Janssen products in oncology, virology, GI, women's health and urology. Samina supported the launch of Janssen's first oral diabetes products and is currently responsible for the strategy and review of scientific responses, development of Academy of Managed Care Pharmacy (AMCP)-formatted formulary dossiers and review of promotional and sales training materials for these products.



Payal Desai, PharmD

**Associate Director,
Medical Information**
Janssen Scientific Affairs, LLC

Payal Desai earned a PharmD degree from the University of Sciences in Philadelphia. Dr. Desai worked in community practice before transitioning to a career in pharmaceutical industry. Over 20 years, Dr. Desai served at several pharmaceutical companies. In her current role at Janssen, she is the Associate Director of Medical Information, where she is responsible for the successful launch of cardiovascular products. She provides strategic medical support, develops internal education plan, and participates in several cross-functional teams. Payal was recognized with a 1-year rotation within the Medical Information Leadership team. She has mentored several Post-doc Fellows and pharmacy students throughout her career.

CURRENT DRUG INFO FELLOWS



Sandra Bai, PharmD

Regulatory Pharmaceutical Fellow
Drug Information Track, PGY2
Current Fellow: 2016 – 2018 Cycle

Sandra is a 2016 graduate of Butler University College of Pharmacy and Health Sciences in Indianapolis, IN. Sandra is currently completing the industry portion of the fellowship. In this role, she serves on the medical information teams for Invokana® and Xarelto® at Janssen Scientific Affairs, LLC. She assists with development and delivery of drug information to healthcare professionals, payors, and consumers as well as review of promotional and non-promotional items for accuracy. In January 2018, she will begin her rotation at the FDA in the Division of Drug Information.



Kiersten Walters, PharmD

Regulatory Pharmaceutical Fellow
Drug Information Track, PGY1
Current Fellow: 2017 – 2019 Cycle

Kiersten graduated from the Purdue University College of Pharmacy in May 2017. Kiersten is currently completing the academic portion of the fellowship. This role includes working at the IU Health Drug Information Center to assist with formulary management, answering drug information requests, and precepting students. Kiersten also assists with the “Principles of Drug Information and Literature Evaluation” course. In January 2018, she will begin her rotation at the Division of Drug Information at the FDA. In July 2018, she will start her rotation in Global Medical Information at Eli Lilly & Company.



Jacqueline Wasynczuk, PharmD

Regulatory Pharmaceutical Fellow
Drug Information Track, PGY1
Current Fellow: 2017 – 2019 Cycle

Jackie is a 2017 graduate of Butler University College of Pharmacy and Health Sciences in Indianapolis, IN. Jackie is currently completing the academic portion of the fellowship where she serves as a Drug Information Specialist in the IU Health Drug Information Center. She also assists with the “Principles of Drug Information and Literature Evaluation” course at Purdue University College of Pharmacy. In January 2018, she will begin her rotation at Janssen Scientific Affairs, LLC.

PAST FELLOW TESTIMONIES

Megan N. Brown, PharmD

Regulatory Affairs Specialist

Time Solutions, LLC/Contractor at the Centers for Disease Control and Prevention (CDC)

Past Fellow: 2015-2017 Cycle



"My favorite aspect of the regulatory pharmaceutical fellowship was that it prepared me to be a strong communicator in a variety of settings-academia, health system, pharmaceutical industry, and public health. I believe that this level of preparation is unique to this particular fellowship program and is its greatest strength. My experience in the fellowship motivated me to pursue a public health communications role, where I am able to communicate health information to health care professionals, the general public, and other audiences on a national scale."

Jay R. Fajiculay, PharmD

Designated Federal Officer, Division of Advisory Committee and Consultant Management

U.S. Food and Drug Administration

Past Fellow: 2014 – 2016 Cycle



"Completing the fellowship has been one of the best career decisions I have ever made. The support and guidance from the preceptors provided an enhanced environment of learning that I will take with me forever. Throughout the fellowship, I had the opportunity to incorporate my interests in digital and technology-based learning across various practice settings. From presenting at local and international conferences, to developing digital applications that are now used in the global arena, the fellowship has prepared me to succeed in beginning my new career."

Bhavini T. Parikh, PharmD

Senior Manager, Medical Information
AstraZeneca

Past Fellow: 2013 – 2015 Cycle



"Completing this fellowship was one of the best decisions I have ever made for my career. The unique program allowed me to step outside of my comfort zone, which in turn led to a great deal of professional development. I made lifelong friends and mentors along the way, and was able to explore various career fields. Upon graduating from the program, these experiences allowed me to feel prepared to start my career in any field of my choice."



PAST FELLOW TESTIMONIES



Andrea M. TenBarge, PharmD

Consultant, Medical Digital Strategy and Capabilities
Eli Lilly and Company
Past Fellow: 2012 – 2014 Cycle

“Choosing to complete the Regulatory Pharmaceutical Fellowship program has been one of the best decisions I have made in my career. Through my fellowship experiences, I discovered my love for innovative digital strategy and was able to land a very unique position which combined my love for medicine with my love for digital and visual media while still being able to continue my love of teaching by precepting fourth year pharmacy students and fellows. It was through my experiences with the fellowship program that led me to where I am today!”



Genevieve L. Ness, PharmD

Director, Christy Houston Foundation Drug Information Center
Assistant Professor, Pharmaceutical, Social and Administrative Sciences
Belmont University College of Pharmacy
Past Fellow: 2011-2013 Cycle

“The skills I obtained during the fellowship serve as the foundation of my career as a faculty member and a director of a drug information center. Bringing the three diverse perspectives to the classroom illustrates to my students the versatility of drug information skills and provides them with insight into diverse career paths. As a drug information center director, I use these skills to seek partnerships with other universities and pharmaceutical companies in addition to managing the output of drug information question responses.”



Kimberly W. Chiu, PharmD

Clinical Outcome Assessments Staff, Office of New Drugs
Food and Drug Administration
Past Fellow: 2010 - 2012

“The Regulatory Pharmaceutical Fellowship's unique format is a great opportunity for professional and personal growth. Professionally I developed a unique skill set which prepared me for challenging positions in a variety of settings. Personally I grew under the strong mentorship of the program's preceptors.”

MEDICATION SAFETY TRACK TIMELINE

MEDICATION SAFETY

July 2018

01

Indianapolis, IN
8 Months

PURDUE
UNIVERSITY

Center for
Medication
Safety
Advancement

Jul. 2018 – Feb. 2019

02

Indianapolis, IN
8 Months

Lilly

Surveillance
and Global
Patient Safety

Mar. 2019 – Oct. 2019

03

Silver Spring, MD
8 Months

FDA

Office of
Surveillance and
Epidemiology

Nov. 2019 – Jun. 2020

June 2020

MEDICATION SAFETY TRACK OVERVIEW

Purdue

The 8-month rotation at Purdue University College of Pharmacy's Center for Medication Safety Advancement (CMSA) will provide the fellow with exposure to academia and the various medication safety initiatives undertaken by CMSA. The fellow will actively participate in practice-based research to foster the discovery and delivery of information and practices to enhance medication safety. There will be numerous opportunities to publish original research and deliver presentations. Additionally, the fellow will have the opportunity to educate students, both didactically and through preceptorship.

Lilly

The fellow will spend an 8-month rotation at Eli Lilly and Company working on the Surveillance team within Global Patient Safety. During this time, the fellow will have opportunities to work cross-functionally between pre- and post-marketed compounds to detect and evaluate adverse events to determine if they are drug-related. The fellow will be involved in safety signal detection and evaluation as well as participating in the development of regulatory documents to gain a foundational understanding of pharmacovigilance responsibilities within industry.

FDA

The fellow will spend the last 8 months of their tenure working in the Office of Surveillance and Epidemiology (OSE) at the FDA. During this time, the fellow will have the opportunity to participate in intra- and inter-center projects in both the pre- and post-market arenas. Additionally, the fellow will utilize adverse drug event reporting data, medical literature, and established knowledge of marketed drug products to assess postmarked safety-related issues and conduct active surveillance work.

MEDICATION SAFETY PRECEPTORS- PURDUE



John Hertig, PharmD, MS

Associate Director, CMSA
Courtesy Clinical Assistant Professor of
Pharmacy Practice
Purdue University College of Pharmacy

Dr. Hertig received his Bachelors of Science in Pharmaceutical Sciences and Doctor of Pharmacy Degree from Purdue University. Following graduation he completed a combined PGY1/PGY2 Masters in Health-System Pharmacy Administration residency at The Ohio State University Medical Center in Columbus, OH. As part of this program, he received a Masters degree in Health-System Pharmacy Administration from the Ohio State University. In his current role he assists in setting and managing the mission and vision of the organization, leads strategic initiatives, forms partnerships, educates, and acts as a catalyst to help improve the lives of patients.



Kyle Hultgren, PharmD

Director, CMSA
Courtesy Clinical Assistant Professor of
Pharmacy Practice
Purdue University College of Pharmacy

Dr. Hultgren is Managing Director of CMSA where he pursues the development of innovative safe medication use practices as well as engaging methods to educate healthcare practitioners and student pharmacists. Dr. Hultgren is a co-author of a certification program in partnership with Purdue University and the Veterans Health Administration on Lean Healthcare and Systems Redesign that has been provided to over 8,000 professionals in health systems nationwide. His current work includes predictive analytics for adverse drug events and utilizing simulation methodologies for training medical professionals on safe medication use practices. He also serves as Chairman of the Rx-SafeNet Practice Based Research Network Advisory Board for community pharmacy based medication safety research in Indiana.

MEDICATION SAFETY PRECEPTORS- ELI LILLY

Jennifer B. Mouser, PharmD

**Director, Safety Surveillance
Global Patient Safety**

Eli Lilly and Company



Jennifer received her PharmD from Butler University. Following graduation, she worked as a retail pharmacist before accepting a safety surveillance position at Eli Lilly in Global Patient Safety. Jennifer served for several years as a safety surveillance scientist identifying and evaluating safety trends and potential safety risks for investigational and approved medications while also continuing to contribute to pharmacy practice as a part-time retail pharmacist. Currently, she is the director of the safety surveillance team which is comprised of scientists who are responsible for the portfolio of investigational and approved drugs as well as scientists who are responsible for monitoring the safety of our device delivery systems.

William P. Brookfield, MS

**Consultant, Safety Surveillance
Global Patient Safety**

Eli Lilly and Company



Bill obtained his pharmacy and pharmacology degrees from Butler University. Following graduation, he began his career in hospital pharmacy and served as a clinical pharmacist, an assistant director of pharmacy and a director of pharmacy over the span of 20 years. In hospital pharmacy, Bill spent time working with two outpatient clinics in diabetes and pulmonology and served as a clinical pharmacist for a family practice residency program. He precepted numerous pharmacy students in administrative and clinical hospital rotations. Bill remains actively involved in student and resident programs at Lilly. He precepts 16 to 18 PharmD students annually at Lilly. He also serves as a pharmacology professor at the University of Indianapolis in their physical therapy program and lectures in continuing education seminars for practicing physical therapists.



MEDICATION SAFETY PRECEPTORS- FDA



Irene Z. Chan, PharmD, BCPS

Commander, U.S. Public Health Service

**Deputy Director, Division of Medication Error
Prevention and Analysis (DMEPA)**

Office of Surveillance and Epidemiology

Food and Drug Administration

CDR Chan received her B.S. and Doctorate degrees in Pharmacy from Rutgers University Ernest Mario School of Pharmacy. Upon graduation, she was called to active duty and assigned to Gallup Indian Medical Center where she completed a PGY1 Pharmacy Practice Residency. She continued with the Indian Health Service for over five years in both inpatient and outpatient pharmacy settings. In 2009, she transferred to FDA. In her current role she leverages her knowledge of regulatory science, human factors, and risk management to provide oversight of safety recommendations regarding drug nomenclature, labels, labeling, packaging, and product design.



S. Christopher Jones, PharmD, MPH

Commander, U.S. Public Health Service

Director, Division of Pharmacovigilance II (DPV)

Office of Surveillance and Epidemiology

Food and Drug Administration

CDR Jones earned his PharmD in 2001 from Virginia Commonwealth University (VCU). He also holds an undergraduate degree in chemistry from VCU and a Master of Public Health degree from Johns Hopkins. During pharmacy school, he joined the US Navy under a scholarship program. After graduation he was commissioned and stationed at Naval Medical Center Portsmouth. He practiced in outpatient, inpatient, and clinic settings. Following his military service, he transitioned to the U.S. Public Health Service at FDA in Silver Spring MD. Today, he is responsible for the post-marketing surveillance of adverse drug events in the Division of Pharmacovigilance II. He is involved in a variety of pharmacovigilance projects and has interests in drug safety and epidemiology.

CURRENT MEDICATION SAFETY FELLOWS

Kaitlyn Dana, PharmD

Regulatory Pharmaceutical Fellow

Medication Safety Track, PGY2

2016 – 2018 Cycle



Kaitlyn received her Bachelors of Science in Pharmacy Studies and Doctor of Pharmacy degree from the University of Connecticut School of Pharmacy in Storrs, Connecticut. Kaitlyn is in her second year of the fellowship program working at Eli Lilly and Company, located in Indianapolis, Indiana in the Global Patient Safety department. At Lilly, Kaitlyn routinely monitors and analyzes adverse event data from a variety of sources. She leads product team meetings to discuss these data and the need for any potential safety updates. In addition, Kaitlyn is assisting with authoring regulatory documents.

Kathryn Marwitz, PharmD, MPH

Regulatory Pharmaceutical Fellow

Medication Safety Track, PGY1

2017 – 2019 Cycle



Kathryn earned her Doctorate of Pharmacy degree from Drake University in Des Moines, Iowa and Master of Public Health degree from Johns Hopkins Bloomberg School of Public Health in Baltimore, Maryland. She is currently at Purdue University College of Pharmacy's Center for Medication Safety Advancement (CMSA). While at CMSA, Kathryn will participate in a number of research projects and legislative initiatives including developing a longitudinal research project from the ground up. Kathryn will help facilitate the Medication Safety and Introduction to the Pharmaceutical Industry courses at Purdue University College of Pharmacy in West Lafayette, Indiana.



PAST FELLOW TESTIMONY

Katelyn Brown, PharmD

Consultant, Diabetes Real World Outcomes

Eli Lilly and Company

Past Fellow: 2013-2015 Cycle



“The Purdue/Lilly/FDA fellowship broadened my horizons to opportunities available to those with a PharmD. My program directors took a vested interest in my development which motivated and helped me obtain my goals by the end of the fellowship. Upon completion of the fellowship, I had developed expertise in project management, medication safety, and leadership which have significantly contributed to the success in my current position.”



ADVERTISING & PROMOTION TRACK

Track Overview

The two-year, Advertising & Promotion track, prepares the fellow with an opportunity to develop an understanding of the FDA regulations, industry codes, policies, and Federal and State laws as it relates to prescription drugs and biologics advertising and promotion activities. The fellow will also have an opportunity to gain experience in the government promotional review process and become familiar with sections of the Federal Food, Drug, and Cosmetic Act and relevant FDA Guidance documents. Finally, the fellow will gain significant experience in academia providing didactic and experiential training of students.

The Advertising & Promotion track plans to recruit a 2019 - 2021 fellow

For more information, please contact:

DrugMarketingFellowship@gmail.com

FELLOWSHIP BENEFITS



Competitive stipend

Reimbursement for relocation and professional travel expenses



Enrollment in the Indiana Pharmacy Teaching Certificate Program

Purdue University benefits package (i.e. health insurance, prescription coverage, vision plan, dental)



Vacation and University holidays

1 year membership in the Regulatory Affairs Professionals Society



APPLICATION PROCESS

The fellow must be a graduate from an ACPE-accredited college of pharmacy, or otherwise eligible for licensure as a pharmacist, prior to the start of the fellowship term.

Preliminary interviews are conducted during PPS at the American Society of Health-System Pharmacists Midyear Clinical Meeting annually. Participation in PPS is not required but is encouraged for applicants.

All interested applicants must submit the following:

1. Letter of intent for one of the two tracks
2. Contact information for three references
3. Curriculum Vitae
4. Official transcripts (electronic copies OK)

All application materials should be submitted electronically to the email contacts below no later than **11:59 pm EST on Wednesday, December 13, 2017.**

Drug Information Track:

DrugInformationFellowship@gmail.com

Medication Safety Track:

MedicationSafetyFellowship@gmail.com

On-site interviews will take place at the FDA in Silver Spring, MD on Friday, January 5, 2018. For more information, please visit our website at:

<http://www.fda.gov/RegPharmFellowship>.



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2018 – 2020 Cycle

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